Het behandelen van kamerritmestoornissen bij patiënten met Tetralogie van Fallot, die een heroperatie ondergaan waarbij de pulmonalisklep wordt vervangen en die risicolopen op kamerritmestoornissen.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21437

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Congenital heart disease

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

The main study endpoints are: (1) achievement of bidirectional conduction block after intraoperative cryoablation, (2) reinducibility of isthmus dependent monomorphic VT after intraoperative cryoablation and (3) occurrence and recurrence of ventricular arrhythmias during follow-up.

Secondary outcome

See primary outcome

Study description

Background summary

Background of the study:

Tetralogy of Fallot (TOF) is the most common severe congenital heart disease and is associated with late morbidity and mortality due to ventricular arrhythmias (VA). Patients with documented or suspected VA usually receive implantable cardioverter defibrillators (ICDs). However, not all VA are life-threatening although an important source of morbidity. In addition, ICDs do not prevent VA therefore additional and/or alternative treatment options are required. Of importance, the majority of VA associated with TOF are monomorphic ventricular tachycardias (VT). We recently could demonstrate that the substrate for the majority of these monomorphic VTs are slow conducting anatomical isthmuses bordered by unexcitable tissue. These slow conducting isthmuses may be the consequence of the initial repair in childhood but may also be due to the abnormal myocardium of the malformation itself. Targeting these isthmuses by catheter ablation has been shown to prevent VT recurrence and is the accepted current approach in clinical practice. Patients after initial total repair of TOF may require a reoperation for pulmonary valve regurgitation. However, simply replacing the valve does not affect the risk for VT. During reoperation potential slow conducting isthmuses can be ablated with the potential to prevent VT recurrence but also VT occurrence and thereby “curing” the isthmus dependent monomorphic VT provided that isthmus block is achieved. Preventive ablation of the slow conducting isthmuses during surgery becomes particular
important if pulmonary valve replacement (PVR) by a homograft is performed. In this case, the homograft may cover important parts of the slow conducting isthmus which makes catheter ablation at a later stage impossible and is the most important reason for ablation failure in patients that present with VT after PVR.

Objective of the study:

1) To evaluate the feasibility and the acute effect of intraoperative cryoablation of the slow conducting anatomical isthmuses (endpoint bidirectional conduction block) and on the re-inducibility of monomorphic isthmus dependent VT.

2) To study the pathomechanism of slow conduction within these isthmuses by comparing histological and electrophysiological characteristics of biopsies in patients after repair of TOF who undergo reoperation and of patients who undergo first total correction.

3) To assess the long-term results of intraoperative cryoablation of the slow conducting anatomical isthmuses on recurrence and occurrence of monomorphic VT.

Study design:

A prospective duo-centre cohort study.

Study population:

Group A: Patients with repaired TOF and accepted for PVR from the age of eight years.

Group B: Patients with TOF who undergo first repair. This group serves only as a control group for the histology of the infundibular muscle which removal is part of the surgical repair.

Intervention:

Intraoperative cryoablation of the slow conducting anatomical isthmuses.

Primary study parameters/outcome of the study:

The main study parameters are: (1) prevalence and characteristics of slow conducting anatomical isthmuses, (2) inducibility of monomorphic isthmus related VT before intraoperative cryoablation, (3) histological and electrophysiological characteristics of the biopsies taken from slow conducting isthmuses (reoperation) and the infundibular muscle which is the most frequent location of a potential slow conducting isthmus later in life (initial repair). The main study endpoints are: (1) achievement of bidirectional conduction block after intraoperative cryoablation, (2) reinducibility of isthmus dependent monomorphic VT after intraoperative cryoablation and (3) occurrence and recurrence of VA during follow-up.

Study objective

Improved understanding of slow conducting anatomical isthmuses in Tetralogy of Fallot and cryoablation of these slow conducting anatomical isthmuses during pulmonary valve replacement might prevent VT re- and occurrence.

Study design

1. Baseline evaluation (electrophysiologic study with right ventricular mapping and biopsies of slow conducting isthmuses and the infundibular muscle).

2. Follow-up: Primary endpoints.

Intervention

The intervention is cryoablation of slow conducting anatomical isthmuses which (potentially) contain critical parts of the VT re-entry circuit.
The first two study endpoints (i, achievement of bidirectional conduction block after intraoperative cryoablation; ii, re-inducibility of isthmus dependent monomorphic VT after intraoperative cryoablation) will be checked during a post-operative electrophysiologic study with mapping of the right ventricle.
The third study endpoint (occurrence and recurrence of ventricular arrhythmias during follow-up) will be achieved by comparing the study cohort with a historical cohort operated/treated by the same team.

Contacts

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Eligibility criteria

Inclusion criteria

Group A: Patients with repaired Tetralogy of Fallot who undergo reoperation for pulmonary valve replacement.

Group B: Patients with Tetralogy of Fallot who undergo primary repair.

Exclusion criteria

Group A: (1) Age younger than 8 years. (2) Inability to comply with the protocol due to hemodynamic instability.

Both groups: (1) Inability to sign informed consent by the patient or his legal representative.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2013
Enrollment:	61
Type:	Anticipated

Ethics review

Positive opinion
Date: 07-10-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39860
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4033
NTR-old	NTR4199
CCMO	NL41727.058.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39860

Study results

Summary results
N/A